

MAY 10 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Yu, *et al.*
Application No: 09/683,003
Filed: November 7, 2001
Group Art Unit: 1616
Confirmation No: 5003
Examiner: Frank I. Choi
Date: May 10, 2006
Attorney Reference: 6601-00
Title: COMPOSITION AND METHOD

TRANSMITTAL LETTER

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Dear Sir:

Transmitted herewith is an Appeal Brief submitted pursuant to 37 C.F.R. §41.37. Please charge the fee for filing a brief in support of an appeal under 37 C.F.R. §41.20(b)(2) to Deposit Account No. 502957.

Please charge any shortage in fees or credit any excess fees during the entire pendency of this Application to Deposit Account No. 502957.

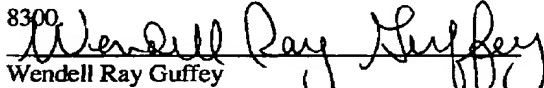
Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being transmitted by facsimile to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on May 10, 2006 at facsimile number 571-273-8300.


Wendell Ray Guffey

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MAY 10 2006

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

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APPEAL BRIEF PURSUANT TO 37 C.F.R. §41.37

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Dear Sir:

Appellants hereby appeal to the Board of Patent Appeals and Interferences from the Final Rejection of Claims 2, 3, 4, and 5 in this application.

Appellants filed a timely Notice of Appeal on March 10, 2006 under 37 C.F.R. §41.31(a) from the action of the Examiner in finally rejecting Claims 2, 3, 4, and 5 in the application.

I. Real Party in Interest

The real party in interest is Hill's Pet Nutrition, Inc., a Delaware corporation having a place of business at 400 SW 8th Avenue, Topeka KS 66603, the assignee of record and a wholly-owned subsidiary of Colgate-Palmolive Company, a Delaware corporation having a place of business at 300 Park Avenue, New York, NY 10022.

II. Related Appeals and Interferences

Appellant knows of no other appeals or interferences that will directly affect or be directly affected by or that have a bearing on the Board's decision in the pending appeal.

III. Status of Claims

Claims 2, 3, 4, and 5 are pending in the application and are the subject of this appeal.

Claims 3, 4, and 5 stand rejected under 35 U.S.C. §112, first paragraph, because the Examiner alleges that the specification, while being enabling for treatment of poor hair growth

or alopecia, does not reasonably provide enablement for prevention of poor hair growth or alopecia.

Claims 3 and 4 stand rejected under 35 U.S.C. §102(b) as being anticipated by McDonald.

Claims 2, 3, 4, and 5 stand rejected under 35 U.S.C. §103(a) as obvious over WO 98/11122, Lee *et al.*, Shields, Jr. *et al.*, Hayek *et al.*, Arthur *et al.*, Ahsan *et al.*, and Messenger.

IV. Status of Amendments

No amendment was filed subsequent to final rejection. Pending Claims 2, 3, 4, and 5 correspond to those submitted on February 13, 2006 in the "RESPONSE TO FINAL OFFICE ACTION." A copy of the pending Claims is included in Appendix A hereto, in accordance with 37 C.F.R. §41.37(c)(1)(viii).

V. Summary of Claimed Subject Matter

The present invention generally provides methods for (1) controlling the rate of hair growth in a dog, cat, or sheep and (2) at least assisting in preventing or treating poor hair growth or alopecia in animals. The methods comprise feeding from about 0.5 to about 4.5 mg of selenium per kg of diet on a dry matter basis to the appropriate animal.

Independent claim 2 is supported in the specification, for example, at page 2, lines 25-30.

Independent claim 2 is supported in the specification, for example, at page 3, lines 6-11.

VI. Grounds of Rejection to be Reviewed on Appeal

- A. Is the invention for the prevention of poor hair growth or alopecia as claimed in pending Claims 2, 3, 4, and 5 enabled under 35 U.S.C. §112, first paragraph, by the specification?
- B. Is the invention as claimed in pending Claims 3 and 4 anticipated under 35 U.S.C. §102(b) by McDonald?
- C. Is the invention as claimed in pending Claims 2, 3, 4, and 5 obvious under 35 U.S.C. §103(a) in view of WO 98/11122, Lee *et al.*, Shields, Jr. *et al.*, Hayek *et al.*, Arthur *et al.*, Ahsan *et al.*, and Messenger?

VII. Argument

The present invention provides methods for (1) controlling the rate of hair growth in a dog, cat, or sheep and (2) at least assisting in preventing or treating poor hair growth or

alopecia in animals. The methods comprise feeding from about 0.5 to about 4.5 mg of selenium per kg of diet on a dry matter basis to the appropriate animal. Appellant respectfully submits that the present invention is enabled by the specification and is novel and non-obvious over the cited references. Specific arguments directed to each outstanding rejection are shown below under the applicable heading.

A. Rejection under 35 U.S.C. §112, first paragraph

1. Applicable Law

The specification is presumably enabling for what it discloses. An assertion by the Examiner that the specification is not enabling for the protection sought in the claims must be supported by evidence or reasoning substantiating the doubts so expressed. *In re Dinh-Nguyen & Stenhagen*, 181 U.S.P.Q. 46 (C.C.P.A. 1974). *In re Bundnick*, 190 U.S.P.Q. 422 (C.C.P.A. 1976). Therefore, the Examiner bears the initial burden of putting fourth a reasonable explanation as to why the scope of protection claimed is not adequately enabled by the description of the invention in the specification. *Fiers v. Revel*, 984 F.2d 1164, 25 U.S.P.Q.2d 1601 (Fed. Cir. 1993). The Examiner must provide evidence to support a non-enablement rejection and cannot simply conclude that the claims are not enabled. Such a conclusion prematurely shifts the burden to Appellant. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971).

The purpose of the enablement requirement is "to ensure that the invention is communicated to the interested public in a meaningful way." The information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention. See, MPEP 2164. The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. See, *U.S. v. Telectronics, Inc.* 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) and *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

2. Rejection of Claims 3, 4, and 5

Claims 3, 4, and 5 stand rejected under 35 U.S.C. §112, first paragraph, because the Examiner alleges that the specification, while being enabling for treatment of poor hair growth or alopecia, does not reasonably provide enablement for prevention of poor hair growth or alopecia. However, the Examiner provided no evidence to support the lack of enablement rejection but instead simply concluded that the specification is not sufficient to support the claimed invention. The burden of proof required by applicable law as set fourth above has

not been met by the Examiner. Further, to permit the Examiner to merely conclude a lack of enablement without supporting evidence or reasoning would shift the burden of proof re enablement to Appellant. Such a burden shift is inappropriate and contrary to applicable law. Given that the Examiner has not met the burden of proof regarding enablement, the rejection under 35 U.S.C. §112, first paragraph, is improper and should be reversed.

Even if the Examiner were presumed to have met the burden of proof regarding enablement, the claims are, contrary to the Examiner's assertions, enabled by the specification. Claims 3, 4, and 5 communicate the invention in a clear and meaningful way such that a skilled artisan could make and use the invention without any undue experimentation. Claims 3, 4, and 5 are directed to methods for "at least assisting in preventing or treating poor hair growth" in animals in need of treatment. The specification (for example, at paragraph 0008 on page 3) states that "enhancing hair growth with selenium supplementation can benefit the management of disorders of the skin, hair follicle and/or hair coat by preventing or treating poor hair growth or alopecia" Further, Appellants have demonstrated by working examples that dogs fed selenium according to the claimed methods have higher rates of hair growth than dogs fed diets with more or less selenium. Thus, one skilled in the art would understand, from reading the specification as a whole, that Appellants have demonstrated that feeding the animal the claimed amounts of selenium will "at least assist in preventing" or treating poor hair growth or alopecia.

Additionally, Appellants have clearly articulated both how to make and use the method of claim 3, including how to use the method to at least assist in preventing poor hair growth or alopecia. For example, at page 2, lines 22-30, Appellants specifically set forth the means for determining the quantity of selenium to be used in the method. Appellants also clearly state that the selenium can be administered in an animal's diet or through specific supplements fed to the animal. See, e.g., page 2, line 35 to page 3, line 2. Therefore, one reasonably skilled in the art could make or use the invention from the disclosures in the specification coupled with information known in the art. Certainly, no undue experimentation would be required to make or use the invention.

Therefore, Appellants respectfully submit that claim 3 is enabled and that the rejection under 35 U.S.C. §112, first paragraph, is improper and should be reversed.

Claims 4 and 5, which depend from claim 3, are enabled under 35 U.S.C. §112, first paragraph, for at least the reasons set forth for claim 3. Therefore, Appellants respectfully

submit that claims 4 and 5 are enabled and that the rejection under 35 U.S.C. §112, first paragraph, is improper and should be reversed.

A. Rejection under 35 U.S.C. §102(b)

1. Applicable Law

Anticipation under 35 U.S.C. §102 is a technical rejection that must meet strict standards; there is no anticipation unless all of the same elements or their equivalents are found in exactly the same situation and united in the same way to perform an identical function in a single prior art reference. *Rite-Nail Packaging Corp. v. Berryfast, Inc.*, 219 U.S.P.Q. 104 (CA 9 1983). See also, *Studiengesellschaft Kohle, m.b.H. v. Dart Industries, Inc.*, 220 U.S.P.Q. 841, 842 (C.A.F.C. 1984) (It is hornbook law that anticipation must be found in a single reference, device or process). A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP 2131, citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed Cir. 1987).

A patent need not teach, and preferably omits, what is well known in the art. See, *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987).

2. Rejection of Claims 3 and 4

Claims 3 and 4 stand rejected under 35 U.S.C. §102(b) as being anticipated by McDonald. Contrary to the Examiner's conclusion, the elements of McDonald and the present invention are not the same nor are they used in the same way to perform an identical function. Claim 3 requires the administration of from about 0.5 to about 4.5 mg of selenium per kg of diet on a dry matter basis for at least assisting in preventing or treating poor hair growth or alopecia in animals. In contrast, McDonald discloses a trial in which 0.1 mg selenium per kg body weight was given orally to ewes and/or lambs initially and at three monthly intervals. See page 433. Thus, the feeding regime (daily in the diet versus periodically as a supplement) and the amount of selenium (discussed in detail below) is significantly different between the cited reference and the claimed invention. Further, the selenium was given by McDonald to evaluate "unthriftiness" and the cause of white muscle disease in the given geographical area. In contrast, the present invention includes selenium in the diet to control poor hair growth and to combat alopecia.

Certainly, the amount of selenium given the animals in the present invention and in McDonald is dramatically different. The claimed invention administers selenium to the animal daily in its diet in amounts of from about 0.5 to about 4.5 mg of selenium per kg of diet on a dry matter basis. McDonald administered 0.1 mg/kg of selenium to the animal at marking and at three month intervals. In McDonald, the animal would have received 0.4 mg/kg selenium total in a one year period.

Just to illustrate the dramatic difference in the amounts, assume that McDonald taught giving the animals 0.1 mg/kg per day (Note that McDonald does not teach daily dosages but teach three monthly dosages). Given this radical but erroneous assumption, a 20 kg McDonald animal would require 2 mg of selenium per day. As is known to all skilled artisans in this area, a 20 kg animal consuming a food that provides about 3800 KCal (the approximate number of KCal in pet and similar animal foods) will require approximately 300 grams (0.3 kg) of food per day. This means that the 20 kg animal will obtain 0.15 to 1.35 mg of selenium per day from the diet claimed in the present invention. Clearly, the amount of selenium to be administered to the animal differs significantly in McDonald and the claimed invention. Even in this fictitious example, the claimed maximum is only about 67% of the amount given in McDonald. In reality, given that McDonald administers selenium on a three month regime rather than a daily diet regime, the amounts of selenium administered in the present invention and in McDonald differ by a factor greater than 90. Therefore, because McDonald does not teach the administration of selenium in amounts that are the same or similar to those claimed in the present invention, the McDonald reference does not teach all of the same elements or their equivalents in exactly the same situation or in the same way to perform an identical function. Therefore, Appellants respectfully submit that claim 3 is not anticipated by McDonald and that the rejection under 35 U.S.C. §102(b) is improper and should be reversed.

Claim 4, which depends from claim 3, is not anticipated by McDonald for at least the same reasons set forth for claim 3.

B. Rejection under 35 U.S.C. § 103(a)

1. Applicable Law

The Supreme Court in *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 U.S.P.Q. 459, 467 (1966) set forth the test for determining obviousness under 35 U.S.C. §103(a). Determining obviousness requires four kinds of factual inquiries:

- (1) the scope and content of the prior art;
- (2) the differences between the prior art and the claimed invention;

- (3) the level of ordinary skill in the field of the invention; and
- (4) any objective indicia of success such as commercial success, long felt need, and copying.

See also, *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 881, 45 U.S.P.Q.2d 1977 (Fed. Cir. 1998).

Further, the initial burden of establishing a basis for denying patentability to a claimed invention rests upon the Examiner. *In re Fine*, 5 U.S.P.Q.2d 1596 (C.A.F.C. 1988). To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP 2143.

In addition, it is well established that there must be some teaching in the references that would provide a motivation or logical reason to a person of ordinary skill in the art to combine the teachings of the references to establish a *prima facie* case of obviousness. See, *W.L. Gore and Associates v. Garlock*, 220 U.S.P.Q. 303 (Fed. Cir. 1983) and *A.S.C. Hospital Systems, Inc., v. Montefiore Hospital*, 221 U.S.P.Q. 929 (Fed. Cir. 1984). When obviousness is based upon a combination of prior art references, there must be a showing of a suggestion or motivation to combine the teachings of those references. See *Gambro Lundia AB v. Baxter Corp.*, 110 F.3d 1573, 1579, 42 U.S.P.Q.2d 1378 (Fed. Cir. 1997) (The absence of such a suggestion to combine prior art references is dispositive in an obviousness determination). See also *B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1582-83, 37 U.S.P.Q.2d 1314, 1318 (Fed. Cir. 1996); *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598-99 (Fed. Cir. 1988). Further, such a combination cannot be based upon "hindsight" that results from the use of applicant's own invention to justify the combination. See *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983) ("To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher"). Case law makes it clear that the best defense against the subtle but powerful attraction of a hindsight-

based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. *See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998) (a teaching or suggestion or motivation to combine references is as an essential evidentiary component of an obviousness holding).

A prior art reference may be considered to teach away when "a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *See In re Gurley*, 27 F.3d 551, 553, 31 U.S.P.Q.2d 1130, 1131 (Fed. Cir. 1994).

2. Rejection of Claims 2, 3, 4, and 5

Claims 2, 3, 4, and 5 stand rejected under 35 U.S.C. §103(a) as obvious over WO 98/11122, Lee *et al.*, Shields, Jr. *et al.*, Hayek *et al.*, Arthur *et al.*, Ahsan *et al.*, and Messenger. Basically, the question in the present case is whether a fair reading of seven (7) separate and demonstratively different references as a whole would suggest combining the references to achieve the present invention to one of ordinary skill in the art at the time of the invention. However, the answer to this question is that claims 2, 3, 4, and 5 are patentable over the combination of the cited references because the Examiner has failed to establish a *prima facie* case of obviousness and, even if the Examiner had established a *prima facie* case of obviousness, a careful reading of the cited references shows that the scope and content of the cited references and the differences between such references and the present invention demonstrate that the references cannot be combined to achieve the present invention. In particular, there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the references to achieve the present invention. In fact, the references cannot be combined to produce the present invention because the cited references, taken either alone or in any combination, do not teach or suggest administering from about 0.5 to about 4.5 mg selenium per kg of diet to an animal for at least assisting in preventing or treating poor hair growth or alopecia or for controlling the rate of hair growth in a dog, cat, or sheep as claimed in claims 2 and 3.

The Examiner's assertion that the cited art suggests the methods of the present invention because the references disclose (1) that selenium is critical to wool production (Lee *et al.*), (2) that selenium is given as a nutritional supplement to animals (WO 98/11122; Shields Jr. *et al.*; Hayek *et al.*), (3) that selenium deficiency results in T3 deficiency (Arthur

et al.), (4) that T3 stimulates hair cell growth and/or metabolism (Ahsan et al.), and (5) the administration of thyroxine, which is converted to T3 by an enzyme which requires selenium, is effective in growing hair in sheep and badgers (Messenger) and the Examiner's conclusion that a skilled artisan would have been motivated to administer similar amounts of selenium to dogs or cats with the expectation that selenium administration would control the rate of hair growth or treat poor hair growth or alopecia is without merit.

Referring to the specification, page 1, lines 19-26, the present invention is directed to administering dietary selenium to an animal in a dosage range that controls the rate of hair growth and combats poor hair growth or alopecia. As clearly stated in the specification, the animal receiving the dietary selenium according to the present invention are otherwise receiving a "nutritious diet." The animals are not selenium deficient animals. The amount of selenium in the disclosed and claimed range is unique and is given throughout the "Summary of the Invention" and the "Detailed Description of the Invention." In contrast, the cited references arguably teach, at most, that animals suffering from selenium deficiency can obtain selenium through nutritional supplements and that the selenium mediates T3 deficiency by acting as a coenzyme. The adverse effects of selenium deficiency is mediated by the administration of relatively small amounts of selenium to the selenium deficient animals when compared to the amounts administered to the animal receiving a nutritious diet according to the present invention.

Further, there is certainly no motivation for a skilled artisan to combine these references to overcome problems caused by alopecia or to promote hair growth using dietary selenium. Alopecia is a loss of hair resulting from various causes, e.g., genetics or an attack of the hair follicle by the immune system. There is no known correlation between such hair loss and selenium, at least not before and without hindsight reliance on the present invention. The present invention is not directed to correcting selenium deficiency or the problems associated with selenium deficiency through the use of periodic nutritional supplement to correct selenium deficiencies as is taught by the cited references. The present invention provides daily dietary selenium in amounts required to combat alopecia.

Similarly, the present invention claims a newly discovered range of dietary selenium. The amounts of selenium received by the animal by consuming dietary (daily) amounts of selenium differs greatly from the amount of selenium received by the animal when administered the selenium supplements as disclosed in the cited references, particularly when the selenium is administered in the relatively small amounts required for

it to functions as a coenzyme. For example, WO 98/11122, page 3, line 12, discloses that 250-300 µg per day is chemopreventive; a dose far smaller than those discovered to be effective for purposes of the present invention. Further, WO 98/11122 requires that the selenium be administered in combination with S-adenosylmethionine (SAM) to be effective, i.e., SAM is required to increase selenium methylation and therefore its bioactivity (page 8, lines 20-24). There is nothing in WO 98/11122 to teach that selenium alone in the diet can be useful to affect hair growth and nothing to motivate a skilled artisan to combine this reference with the six other cited references to achieve the present invention. Indeed, WO 98/11122 teaches away from the present invention. A skilled artisan would be led to believe that selenium alone is not bioactive and would not be effective in the diet or otherwise unless it was administered in combination with other compounds that increase its bioactivity while avoiding toxic amounts.

Therefore, the Examiner has not established a *prima facie* case for obviousness because no motivation to combine references teaching using relatively small amounts of selenium administered periodically to combat health problems caused by selenium deficiency to achieve an invention; and invention the claims feeding a diet containing selenium in relatively high amounts to promote additional hair growth in animals receiving a nutritious diet and not suffering from selenium deficiency.

Further, even assuming the Examiner could establish a *prima facie* case of obviousness, the scope and content of the prior art and the differences between the claimed invention and the cited prior art do not support a conclusion of obviousness. The Examiner's assertion that a skilled artisan could administer similar amounts (those amounts taught in the cited references) of selenium to dogs or cats with the expectation that selenium administration would control the rate of hair growth or treat poor hair growth or alopecia is not supported by a fair reading of the references and the present application.

In Arthur, selenium functions as a coenzyme for the disclosed selenozyme. Selenium is important because it is involved in thyroid hormone metabolism and increases the severity of iodine deficiencies. There is nothing in the reference to motivate a skilled artisan to conclude that this reference can be combined with other references to achieve an invention directed to alopecia. This is particularly true since the reference is directed to problems associated with selenium deficiency and the current invention feeds daily doses of dietary selenium to animals that are not selenium deficient. The present invention results in relatively high amounts of selenium being administered compared to that taught by the

references. In addition, the present invention administers selenium to animals that are not required to be selenium deficient to achieve the desired results, controlling hair growth and combating alopecia. Also, as discussed above, WO 98/11122 teaches that cofactors such as SAM must be present to increase bioactivity at the dosages disclosed in the reference. Therefore, not only is there not a motivation to combine the references to achieve the dietary amounts of the present invention, but the references cannot be combined to achieve such amounts. Given the teaching that selenium is a coenzyme and that cofactors such as SAM are required to increase bioactivity, the skilled artisan cannot read the references and have a reasonable expectation of success in determining a dietary dosage useful for animals for the claimed purposes. There is nothing in WO 98/11122 to teach how SAM influences the amount of selenium required by an animal or how much selenium would be required without something to increase the bioactivity of selenium. Only after reading the present application could the skilled artisan determine that daily dietary selenium is useful for promoting hair growth determine the appropriate range of dietary selenium useful to promote hair growth in otherwise nutritiously fed animals.

In fact, the references teach away from the present invention. WO 98/11122 teaches at page 2, lines 17-25 that daily intake of selenium has the benefit of stimulating the immune system. Certainly, for alopecia caused by an overactive immune system attacking the hair follicle, one would not want to stimulate the immune system and cause further damage to the hair follicle. Quite the opposite, the reference would suggest that avoiding the daily intake of selenium could avoid stimulating the immune system and help prevent alopecia and other autoimmune diseases. Only now that the present invention teaches that daily intake of selenium in the claimed amounts is useful for preventing and treating alopecia and the impermissible use of hindsight can the references be combined to achieve the present invention. Thus, not only is motivation to combine the references is lacking but they cannot be combined to achieve the present invention, particularly since they teach away from the present invention.

Also, nothing in a combination of the cited references teaches or suggests administering the amounts or ranges of selenium recited in claims 2 and 3. The cited references discuss various amounts of selenium (0.1 to 0.3 mg in Lee et al.; 0.4 mg/kg in Shields, Jr. et al.; 0.27 mg/kg in Hayek et al.; 0.001 mg to about 5 mg in WO 98/11122) in various nutritional supplements. Such disparate individual teachings are insufficient to arrive at the claimed range of from about 0.5 to about 4.5 mg selenium per kg of diet.

Further, even if the amounts of selenium are "similar" as argued by the Examiner, Example 1 at pages 3-5 of the specification shows that dogs fed selenium in accordance with the methods of the invention had higher rates of hair growth than dogs fed diets containing amounts of selenium outside of the claimed range. Thus, without reference to Appellant's results, one skilled in the art would not interpret the disparate teachings of the cited references, which contain amounts outside of the claimed ranges, as teaching or suggesting the claimed range of from about 0.5 to about 4.5 mg selenium per kg of diet.

Similarly, the references teach administering selenium (or selenium in combinations with other compounds to increase its bioactivity) to combat problems caused by selenium deficiency. The present invention, in contrast, administers selenium (alone, not in combination with other compounds) to animals that have received a nutritious diet and are therefore not suffering from a selenium deficiency. Given this dramatic difference in the scope and content of the cited references and the differences between the claimed invention and the cited prior art, a conclusion of obviousness based on a combination of the cited references is unjustified.

Basically, the differences between the cited references and the present invention do not permit a conclusion of obviousness based on any combination of the cited references. Those differences include:

- (1) the animals administered selenium (selenium deficient in the prior art vs. nutritiously fed in the present invention),
- (2) the manner in which selenium is administered to the animal (in combination with compounds that increase selenium bioactivity in the prior art vs. alone in the present invention),
- (3) the dramatically different amounts and different dosage schedules (relatively small dosages given periodically vs. relatively larger amounts fed in a daily diet), and
- (4) the results (overcoming health problems caused by selenium deficiency in the prior art vs. controlling hair growth and combating poor hair growth or alopecia in nutritiously fed animals in the present invention).

Therefore, Appellants submit that there is no suggestion or motivation, either in the cited references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the references to achieve the present invention. Further, even if combined, the references do not teach all of the claimed limitations or provide a reasonable expectation of success such that a *prima facie* case of

obviousness can be established. Further, scope and content of the cited references and the differences between the claimed invention and the cited prior art are sufficient to overcome any conclusion of obviousness. Thus, claims 2 and 3 are not obvious under 35 U.S.C. §103(a) over any combination of the cited references. Because independent claim 3 is not obviousness, it is respectfully submitted that a case of obviousness for dependent claims 4 and 5 cannot be maintained.

C. Conclusion

Appellant submit that the arguments provided above show that none of the grounds of rejection against the present claims can be upheld. All claims are believed to be allowable. Appellant respectfully requests reversal of all grounds of rejection of the present claims.

VIII. Claims Appendix

The Board's attention is respectfully drawn to Appendix A hereto.

IX. Evidence Appendix


No evidence is entered in this Appeal Brief.

X. Related Proceedings Appendix

No related proceedings are identified herein.

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Appendix A

Claims Pending on Appeal

1. (canceled).
2. (previously presented) A method for controlling the rate of hair growth in a dog, cat, or sheep comprising feeding the dog, cat, or sheep from about 0.5 to about 4.5 mg of selenium per kg of diet on a dry matter basis.
3. (previously presented) A method for at least assisting in preventing or treating poor hair growth or alopecia in animals in need of said treatment comprising feeding the animal from about 0.5 to about 4.5 mg of selenium per kg of diet on a dry matter basis.
4. (original) The method in accordance with claim 3 wherein the animal is a dog, cat, or sheep.
5. (previously presented) The method in accordance with claim 3 wherein the animal is a dog or cat.